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| 10/811,839 | 03/30/2004 | Theoharis C. Theoharides | 2003133.125US11 | 3048 |

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| EXAMINER | |
|---|---|
| HAGOPIAN, CASEY SHEA | |
| ART UNIT | PAPER NUMBER |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/811,839 | THEOHARIDES, THEOHARIS C. | |
| | Examiner | Art Unit | |
| | Casey S. Hagopian | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *45-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9-11-2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

Receipt is acknowledged of applicant's Amendment/Remarks filed 7/17/2009 and IDS filed 9/11/2009.

Claims 45, 48, 51-56, 58 and 60-63 have been amended. Claims 1-44 were previously cancelled. Claim 64 is newly added. Thus, claims 45-64 are currently pending.

***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) and/or 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Applicant claims the instant application is a CIP of PCT/US02/00476 which is a CIP of USPA 09/771,669 which is a CIP of 09/056,707.

The disclosure of the prior-filed application, Application No. '476, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35

U.S.C. 112 for one or more claims of this application. The corresponding published document for '476 is WO 2002/060393. Regarding claim 45, applicant has removed the limitations "pelvic inflammatory condition" and "polyunsaturated fatty acid", however applicant argues that '393 contains support for "folic acid". The examiner concedes that folic acid is mentioned in the '393 document, however not in the capacity that applicant is claiming said limitation. Claim 45 claims a composition comprising a sulfated proteoglycan and at least one ingredient selected from the group consisting of... folic acid. '393 only discusses the use of folic acid as an additive and not as an essential ingredient (see claims 1, 29 and 33; examples; page 6, lines 31-32). Thus, '393 does not have support for "folic acid' as it is being claimed in instant claim 45. Regarding amended claims 60-63, endometriosis is not supported by '393. Regarding new claim 64, polyunsaturated fatty acid is also not supported by '393.

Accordingly, Applicants are not afforded priority to said application '476 or its parent applications '669 and '707. Therefore, without evidence to the contrary, the filing date of 3/30/2004 is deemed the priority date of the instant application.

**WITHDRAWN REJECTIONS**

Applicant's amendment renders the rejection(s) under 35 USC 112, 1st and 2nd paragraphs moot. Thus, said rejections have been withdrawn.

Applicant's amendment renders the rejection under 35 USC 102 over Crea moot. Specifically, the previous claims were drawn to a method of treating inflammatory pelvic

disease. The claims are now drawn to a method of treating endometriosis. Crea is silent to endometriosis. Thus, said rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Yui et al., Barella et al. and Sugamata (see *New Rejections* section below).

## MAINTAINED REJECTIONS

The following rejections have been maintained from the previous Office Action dated 4/17/2009:

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Amended claims 45-47 and 52 and newly added claim 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Florio (WO 97/21434).

Florio teaches nutritional supplements for treating arthritis comprising gamma linolenic acid, the polyunsaturated fatty acids eicosapantaenoic acid (EPA) and

docosahexaneoic acid (DHA), the sulfated proteoglycans chondroitin sulfate, N-acetyl glucosamine sulfate and glucosamine sulfate, and manganese aspartate (abstract). Florio further exemplifies amounts of said ingredients including 250mg of glucosamine, 100 mg of chondroitin sulfate, 400 mg of EPA and 300 mg of DHA (page 13, lines 21, 22 and 25).

Thus, the disclosures of Florio render the instant claims anticipated.

***Response to Arguments***

Applicant's arguments filed 7/17/2009 with respect to the rejection under 35 USC 102 over Florio have been fully considered and are persuasive in part. The amendments to claims 48, 51 and 53-59 render said rejection over *those* claims moot. Thus, the rejection has been withdrawn from said claims. However, applicant's arguments are found unpersuasive regarding claims 45-47 and 52.

Applicant argues that the amended claims no longer require polyunsaturated fatty acids yet the composition taught by Florio requires polyunsaturated fatty acids. Applicant concludes that because the polyunsaturated fatty acids are required by Florio, Florio does not disclose each and every element of claim 45 and cannot anticipate claim 45. See pages 7-8 of Remarks.

In response, it is respectfully submitted that the instant claims contain open-ended "comprising" language that allows for other ingredients to be included in the composition. Claim 45 reads,

> A composition comprising a sulfated proteoglycan and at least one ingredient selected from the group consisting of a sulfated hexosamine, a flavonoid, S-adenosylmethionine, a histamine-1

receptor antagonist, a histamine-3 receptor agonist, a CRH antagonist, caffeine, folic acid, and a polyamine.

Florio teaches a sulfated proteoglycan (i.e., chondroitin sulfate) and a sulfated hexosamine (i.e., glucosamine sulfate and N-acetyl glucosamine sulfate). Instant claim 52 claims the particular sulfated hexosamine, D-glucosamine sulfate (i.e., glucosamine sulfate). It is noted that new claim 64 further adds a polyunsaturated fatty acid. Thus, Florio reads on the claims as they are currently written.

For these reasons, Applicant's arguments are found unpersuasive. Said rejection under 35 USC 102 over Florio is maintained.

Claims 45-56 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Theoharides (WO 02/060393 A2).

Theoharides teaches proteoglycan compositions for treatments of inflammatory conditions comprising a sulfated proteoglycan such as chondroitin sulfate and one or more of a hexosamine sulfate such as D-glucosamine sulfate, a flavone such as quercetin, an refined kernel olive oil that increases absorption, S-adenosylmethionine (SAM), a histamine-1 receptor antagonist, a histamein-3 receptor agonist, a CRH antagonist, caffeine and a polyamine (abstract). Theoharides teaches other suitable proteoglycans including keratin sulfate, dermatan sulfate and sodium hyaluronate (page 6, lines 1-2), other suitable flavones including myricetin, genistein and kaempferol (page 6, lines 10-11), suitable histamine-1 receptor antagonists including hydroxyzine, azelastine, azatadine and cyproheptadine (page 7, lines 1-3). Theoharides further

teaches preferred concentrations of the proteoglycan, hexosamine sulfate and flavones to be 10-3000 mg, SAM to be 3-1000 mg and unrefined kernel olive oil to be 900-1200 mg (page 7, lines 21-28). Example 10 exemplifies the particular combination of chondroitin sulfate, quercetin and hydroxyzine and Example 14 exemplifies the particular combination of chondroitin sulfate, myricetin and hydroxyzine.

Thus, the disclosures of Theoharides render the instant claims anticipated.

***Response to Arguments***

Applicant's arguments filed 7/17/2009 with respect the rejection under 35 USC 102 over Theoharides have been fully considered but they are not persuasive.

Applicant argues that priority has been perfected and Theoharides is no longer prior art. See pages 8-9 of Remarks.

In response, it is respectfully submitted that for the same reasons as discussed above in *Priority* section of *this* Office Action, Applicant's arguments are found unpersuasive. Said rejection under 35 USC 102 over Theoharides is maintained.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 57 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theoharides (WO 02/060393 A2).

Theoharides teaches the elements discussed above. Specifically, Example 10 teaches a composition comprising 50 mg of chondroitin sulfate, 400 mg of quercetin and 50 mg of hydroxyzine and Example 14 teaches a composition comprising 500 mg of myricetin, 200 mg of chondroitin sulfate and optionally, hydroxyzine.

With regards to instant claim 57, Theoharides is silent to the amount of quercetin being 50-300 mg and with regards to clam 59, Theoharides is silent to myricetin and hydroxyzine each in the amount of 50-300 mg.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include said ingredients in the amounts claimed with a reasonable expectation of success because the prior art teaches broad ranges inclusive of the claimed amounts as well as utilize the claimed ingredients in the claimed amounts in other formulations. Thus, in light of the teachings of Theoharides it would have been obvious to one of ordinary skill in the art at the time of the invention to optimize the compositions by way of routine experimentation.

The teachings of Theoharides render the instant claims obvious.

***Response to Arguments***

Applicant's arguments filed 7/17/2009 with respect the rejection under 35 USC 103 over Theoharides have been fully considered but they are not persuasive.

Applicant argues that priority has been perfected and Theoharides is no longer prior art. See page 12 of Remarks.

In response, it is respectfully submitted that for the same reasons as discussed above in *Priority* section of *this* Office Action, Applicant's arguments are found unpersuasive. Said rejection under 35 USC 103 over Theoharides is maintained.

Claims 45-48 and 51, 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsberg et al. (US 2006/0210551 A1).

Lindsberg et al. teaches compositions comprising a mast cell degranulation-blocking agent and/or a mast cell activation-blocking agent (Abstract). Lindsberg et al. teaches that a preferable mast cell degranulation-blocking agent is a histamine-1 receptor antagonist including hydroxyzine (paragraphs [0036]-[0037]). Lindsberg et al. further teaches other agents that inhibit mast cell secretion and proliferation including flavonoids such as quercetin optionally in combination with chondroitin sulfate (paragraph [0038]). Lindsberg et al. also teaches that the mast cell degranulation-blocking agent and/or a mast cell activation-blocking agent is administered in a therapeutically effective amount, typically about 0.05-100 mg per kg body weight of the patient (paragraph [0040]). Lindsberg et al. also teaches that unit dosage forms preferably contain about 0.1 to about 1000 mg of active compound (paragraph [0044]).

A person of ordinary skill in the art would have been motivated to combine chondroitin sulfate, hydroxyzine and/or quercetin and because Linsdberg et al. teaches all of the agents to be used for the same purpose (i.e., art recognized equivalents). A practitioner would have reasonably expected a composition effective in blocking mast cell granulation.

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose .... The idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846,850,205 USPQ 1069, 1072 (CCPA 1980).

Therefore, in Lindsberg et al., it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the claimed invention was made to have combined chondroitin sulfate, hydroxyzine and/or quercetin in order to form a new composition effective in blocking mast cell granulation.

Thus, the teachings of Lindsberg et al. render the instant claims obvious.

***Response to Arguments***

Applicant's arguments filed 7/17/2009 with respect to the rejection under 35 USC 103 over Lindsberg et al. have been fully considered and are persuasive in part. The amendments to claims 52-55 render said rejection over *those* claims moot. Thus, the rejection has been withdrawn from said claims. However, applicant's arguments are found unpersuasive regarding claims 45-48, 51, 56 and 57.

Applicant argues that priority has been perfected and Lindsberg et al. is no longer prior art. See page 10 of Remarks.

In response, it is respectfully submitted that for the same reasons as discussed above in *Priority* section of *this* Office Action, Applicant's arguments are found unpersuasive. Said rejection under 35 USC 103 over Lindsberg et al. is maintained.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 45-59 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 and 15-27 of U.S. Patent No. 6,984,667 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter in the claims of the patent '667 anticipates the subject matter of the claims in the instant application.

For instance, claim 1 of '667 is drawn to a composition comprising a non-bovine proteoglycan and unrefined kernel olive oil, and one or more of D-hexosamine sulfate, a flavonoid, S-adenosyimethionine, and a histamine-1-receptor antagonist, in an appropriate excipient or vehicle.

Claim 45 of the instant application is drawn to a composition comprising a sulfated proteoglycan and at least one ingredient selected from the group consisting of a sulfated hexosamine, a flavonoid, S-adenosylmethionine, a histamine-1 receptor antagonist, a histamine-3 receptor agonist, a CRH antagonist, caffeine, folic acid, a polyunsaturated fatty acid, and a polyamine.

Claims 45-50, 53, 55 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 7,115,278 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter in the claims of the patent '667 anticipates the subject matter of the claims in the instant application.

For instance, claim 1 of '278 is drawn to a composition comprising, in mg, chondroitin sulfate, 25-75; rutin, 25-75; quercetin, 50-150; S-adenosylmethionine, 150-250; folic acid, 0.17-0.37; fish oil polyunsaturated fatty acids, 150-200; microfiltered olive kernel extract, 200-300; bitter willow extract, 10-50; suspension agents, 50-70

Claim 45 of the instant application is drawn to a composition comprising a sulfated proteoglycan and at least one ingredient selected from the group consisting of a sulfated hexosamine, a flavonoid, S-adenosylmethionine, a histamine-1 receptor antagonist, a histamine-3 receptor agonist, a CRH antagonist, caffeine, folic acid, a polyunsaturated fatty acid, and a polyamine.

***Response to Arguments***

Applicant's arguments filed 7/17/2009 have been fully considered but they are not persuasive.

At page 12 of Remarks it states, "Applicant is filing a terminal disclaimer for U.S. Patent Nos. 6,984,667 and 7,115,278 with this Response", however it appears that no terminal disclaimers were filed with said Response.

Thus, at this time, the Double Patenting rejections are maintained.

**NEW REJECTIONS**

In light of Applicant's amendments, the following rejections have been newly added:

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included *here* can be found in a prior Office action.

Claims 60 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Yui et al. (US 2002/0150605), Barella et al. (WO 03/068202) and Rang et al. (US 2001/0009680).

Yui et al. teaches the treatment of endometriosis comprising a biodegradable polymer (paragraph [0032]). A particular biodegradable polymer taught is chondroitin sulfate (Example 2; paragraph [0081]).

Barella et al. teaches treating angiogenesis-associated pathologies including endometriosis (claims 1 and 6) with compounds such as quercetin or myricetin (claim 4).

Rang et al. teaches methods of treating endometriosis (paragraphs [0061] and [0202]; claim 2). Said methods include compositions comprising at least one of the following most preferred compounds phosphocholine, glycerol-phosphocholine or glucosamine-3-sulfate (paragraph [0200]).

Each agent, chondroitin, glucosamine and quercetin, are all separately taught in the art to treat endometriosis. It is *prima facie* obvious to combine compositions known in the art for the same purpose to create a new composition for the very same purpose. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine chondroitin sulfate, glucosamine sulfate and quercetin in order to create a new composition to effectively treat endometriosis.

Claims 60, 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Yui et al. (US 2002/0150605), Barella et al. (WO 03/068202) and Sugamata (US 2004/0024016).

Yui et al. teaches the treatment of endometriosis comprising a biodegradable polymer (paragraph [0032]). A particular biodegradable polymer taught is chondroitin sulfate (Example 2; paragraph [0081]).

Barella et al. teaches treating angiogenesis-associated pathologies including endometriosis (claims 1 and 6) with compounds such as quercetin or myricetin (claim 4).

Sugamata teaches the treatment of endometriosis comprising an antiallergic agent such as hydroxyzine (abstract; paragraph [0009]).

Each agent, chondroitin, hydroxyzine, quercetin and myricetin, are all separately taught in the art to treat endometriosis. It is *prima facie* obvious to combine compositions known in the art for the same purpose to create a new composition for the very same purpose. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine chondroitin sulfate, hydroxyzine and either quercetin or myricetin in order to create a new composition to effectively treat endometriosis.

***Conclusion***

All claims have been rejected; no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Casey S Hagopian/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615